

### **REMARKS**

The above-identified application has been considered in view of the Office Action that was mailed on January 9, 2009. Claims 1-35 are currently pending. By the present Amendment, Applicant has amended independent claims 1, 19, 28, 31, and 33. Applicant respectfully submits that the amendments to independent claims 1, 19, 28, 31, and 33 effected herein do not introduce any new subject matter, and are fully supported by the specification as originally filed. In view of these amendments, and the following remarks and arguments, Applicant respectfully submits that claims 1-35 are allowable over the references of record, and accordingly, respectfully requests reconsideration and allowance of these claims.

Claims 1-5, 7-9, 12-16 and 18-35 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,215,521 to Cochran, *et al.* (hereinafter "Cochran") in view of U.S. Patent No. 5,149,159 to Bardes, *et al.* (hereinafter "Bardes"). Applicant respectfully submits, however, that the combination of Cochran and Bardes fails to suggest the subject matter of claims 1-5, 7-9, 12-16, and 18-35 as a whole.

35 U.S.C. §103(a) indicates that "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art," then the subject matter is not patentable. (Emphasis added). MPEP §2141(III) elaborates further, requiring that a rejection under 35 U.S.C. §103 must be based on one or more prior art references that teach or suggest all the claim limitations, or that the rejection must explain why

it would have been obvious to one of ordinary skill in the art to include any elements and features recited in the claims that are absent from the cited reference(s).

Independent claim 1 recites “[a] tissue removal device” that includes, *inter alia*, a bag “having folds including at least one transverse fold” that is repositionable between unfolded position and folded conditions, “whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.”

Independent claim 19 recites “[a] method of collapsing a bag of a tissue removal device” that includes the steps of, *inter alia*, providing a tissue removal device with a bag that is repositionable between unfolded and folded positions, and:

folding the bag transversely with respect to the longitudinal axis such that a first transverse fold is formed . . . whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.

Independent claim 28 recites “[a] minimally invasive tissue removal device” that includes, *inter alia*, a bag that is repositionable between unfolded and folded positions, wherein the bag is:

folded over onto itself so as to form at least one transverse fold . . . such that an axial length of the bag assembly is increased and a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, that is relatively smaller as compared to a distal portion of the tissue removal device including a like bag, in a folded position, that is devoid of said at least one transverse fold.

Independent claim 31 recites “[a] minimally invasive tissue removal device” that includes, *inter alia*, a bag that is repositionable between unfolded and folded positions, wherein:

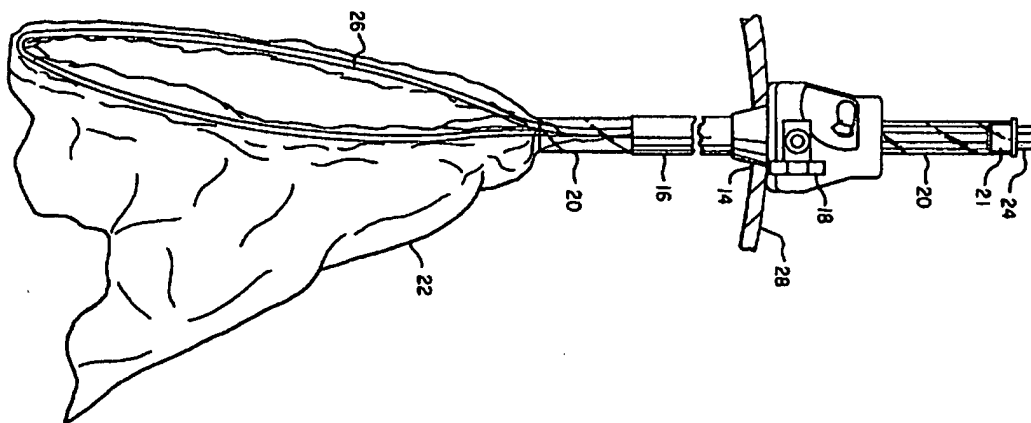
the bag is folded over onto itself so as to form at least one fold extending along an axis that is substantially non-parallel and non-orthogonal to the longitudinal axis of the shaft, whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.

Independent claim 33 recites “[a] method of collapsing a bag of a tissue removal device” that includes the steps of, *inter alia*, “providing a minimally invasive tissue removal device” including a bag that is repositionable between unfolded and folded positions, and:

folding the bag such that at least one transverse fold is formed, the at least one transverse fold extending transversely with respect to the longitudinal axis, whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension,

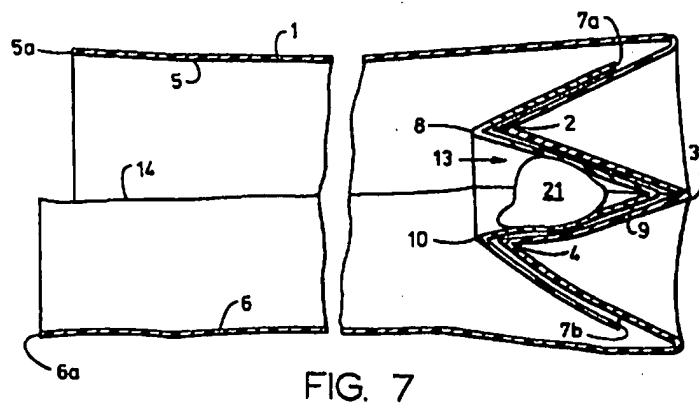
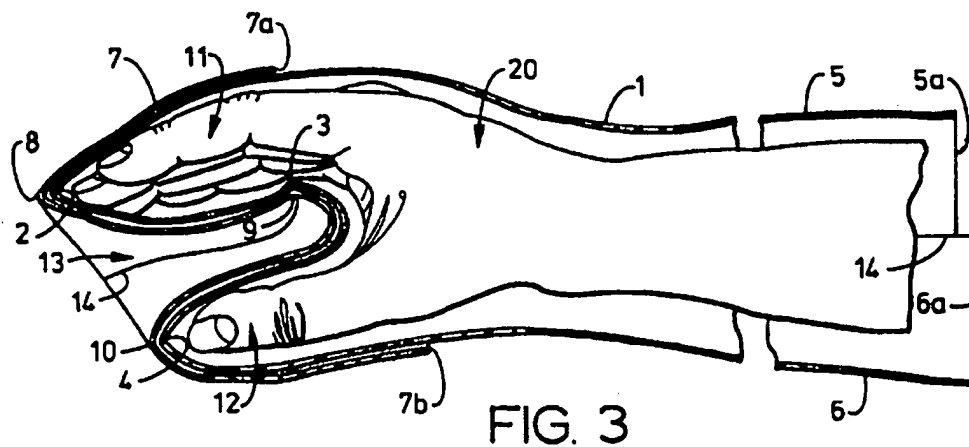
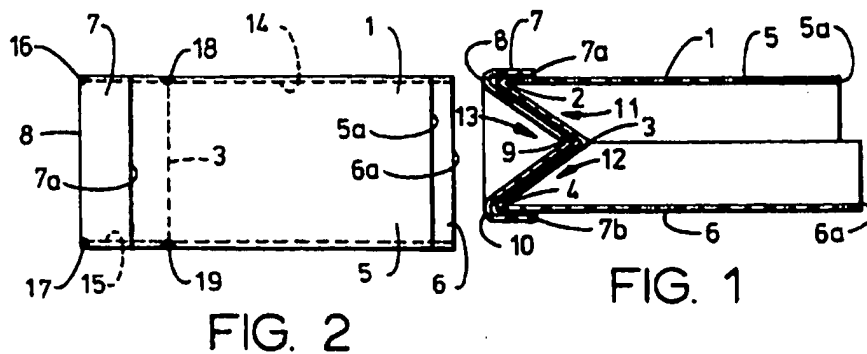
when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.

Cochran relates to an organ retrieval apparatus including an entrapment envelope 22 that is inserted into an inflated body cavity through an elongate sheath 20. (See col. 8, lines 12-18; see FIG. 4 reproduced below).



**FIG. 4**

Bardes relates to “a disposable collector and container in the form of a glove-like bag.” (Col. 1, lines 8-9). Specifically, Bardes discloses a collector including a strip 1 that is connected to a second ply 7. (See col. 3, lines 49-64; see FIGS. 1, 2 reproduced below). The strip 1 is folded along transverse fold lines 2, 3, 4 to form a closed end with a gusset having a “W” shape. (See col. 3, lines 54-56; see FIGS. 1, 7 reproduced below). The closed, gusseted end of the collector forms three pockets, i.e., two interior pockets 11, 12 and one exterior pocket 13. (See col. 4, lines 4-7; see FIGS. 1, 3, 7 reproduced below).



In the Office Action, the entrapment envelope 22 described in Cochran was characterized as the “bag” recited in claims 1-5, 7-9, 12-16, and 18-35. While the Examiner argued that the Cochran envelope 22 is capable of folding transversely, the Examiner acknowledged that the envelope 22 fails to include the at least one transverse fold also included as part of the claimed subject matter, and relied upon Bardes for disclosure of this concept. (See Final Office Action, page 3).

Regarding Bardes, with reference to FIG. 7 (reproduced above), the Examiner stated that:

Bardes et al. disclose[s] a sample retrieval instrument having a bag having at least one transverse fold. The device disclosed by Bardes et al. includes a pouch having a shape for the collection and removal of sample. The pouch includes a first and second edge with bag folds including at least one transverse fold extending from the first edge toward the second edge such that an angle less than 90 degrees is defined relative to the longitudinal axis.

As an initial matter, Applicant respectfully submits that the Examiner’s rejection fails to establish a *prima facie* case of obviousness under 35 U.S.C. §103(a). The Examiner’s rejection blanketly asserts that Bardes discloses the claimed bag, and fails to identify the specific structure in Bardes that is relied upon for disclosure of the at least one transverse fold recited in the claims. In doing so, the Examiner has deprived Applicant of the ability to respond in any specific way to the suppositions made in the Office Action, and thus, to traverse the rejection by highlighting the patentable distinctions between the claimed subject matter and that which is disclosed in the references of record. As such, Applicant respectfully submits that the rejection of claims 1-5, 7-9, 12-16, and 18-35 under 35 U.S.C. §103(a) over the combination of Cochran

and Bardes is legally insufficient as presented in the Office Action, and accordingly, respectfully requests withdrawal thereof.

Overlooking the legal deficiencies of the rejection, Applicant highlights that, according to the present disclosure, the bag 40 recited in the pending claims is repositionable between unfolded and folded positions, e.g., in preparation for packaging, as seen below in the transition between FIGS. 3 and 4. (See page 13, lines 15-18). Specifically, the present disclosure states that repositioning the bag 40 along a transverse fold 47 “has been found to produce a low profile folded bag, such that smaller diameter tubes can be used.” (See page 13, lines 18-20). In other words, including the transverse fold 47 in the bag 40 allows for a reduction in the profile and dimensions of the bag 40.

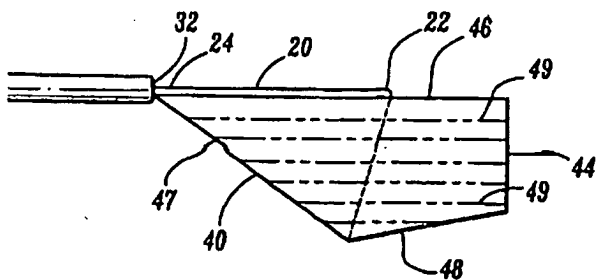


FIG. 3

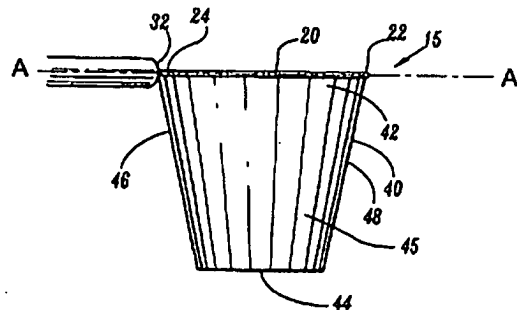


FIG. 4

In contrast, Bardes indicates that the folds 2, 3, 4 form the aforementioned gusset in the collector having three pockets 11, 12, 13. While the fold 2, 3, 4 allow the overall axial

dimension, or length, of the collector to be reduced by folding the collector inwardly, the folds 2, 3, 4 do nothing to reduce the transverse profile or dimensions of the collector. As can be appreciated through reference to FIGS. 1, 2, and 7 of Bardes (reproduced above), the common transverse dimension (width) shared by the strip 1 and the second ply 7 is the same as that of the collector. In other words, the transverse dimension of the Bardes collector is the same before and after folding.

As there is no disclosure, teaching, or suggestion in Bardes to include additional folds that the combination of Cochran and Bardes fails to disclose, or even suggest, “[a] tissue removal device” that includes, *inter alia*, a bag “having folds including at least one transverse fold” that is repositionable between unfolded position and folded conditions, “whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold,” as recited in independent claim 1. (Emphasis added).

Applicant respectfully submits that the combination of Cochran and Bardes also fails to disclose, or even suggest, “[a] method of collapsing a bag of a tissue removal device” that includes the steps of, *inter alia*, providing a tissue removal device with a bag that is repositionable between unfolded and folded positions, and folding the bag such that at least one transverse fold is formed, “whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a



transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold,” as recited in amended independent claim 19. (Emphasis added).

Likewise, Applicant respectfully submits that the combination of Cochran and Bardes fails to disclose, or even suggest, the “minimally invasive tissue removal device” recited in amended independent 28, which includes, *inter alia*, a bag that is repositionable between unfolded and folded positions, wherein the bag is:

folded over onto itself so as to form at least one transverse fold . . . such that an axial length of the bag assembly is increased and a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, that is relatively smaller as compared to a distal portion of the tissue removal device including a like bag, in a folded position, that is devoid of said at least one transverse fold. (Emphasis added).

Similarly, Applicant respectfully submits that the combination of Cochran and Bardes fails to disclose, or even suggest, the “minimally invasive tissue removal device” recited in amended independent claim 31, which includes, *inter alia*, a bag that is repositionable between unfolded and folded positions, wherein:

the bag is folded over onto itself so as to form at least one fold extending along an axis that is substantially non-parallel and non-orthogonal to the longitudinal axis of the shaft, whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like

bag, in a folded position, devoid of said at least one transverse fold. (Emphasis added).

Likewise, Applicant respectfully submits that the combination of Cochran and Bardes fails to disclose, or even suggest, the method recited in amended independent claim 33, which recites the steps of, *inter alia*, “providing a minimally invasive tissue removal device” including a bag that is repositionable between unfolded and folded positions, and:

folding the bag such that at least one transverse fold is formed, the at least one transverse fold extending transversely with respect to the longitudinal axis, whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold. (Emphasis added).

For at least the reasons set forth above, *inter alia*, Applicant respectfully submits that neither Cochran, nor Bardes, nor any proper combination thereof, discloses or suggests the subject matter of amended independent claims 1, 19, 28, 31, and 33 as a whole, and therefore, that amended independent claims 1, 19, 28, 31, and 33 are allowable over Cochran in view of Bardes under 35 U.S.C. §103(a) as presented herein.

Since claims 2-5, 7-9, 12-16, 18, 20-27, 29, 30, 32, 34, and 35 depend either directly or indirectly from amended independent claims 1, 19, 28, 31, and 33, and include each element recited therein, for at least the reasons that amended independent claims 1, 19, 28, 31, and 33 are allowable over Cochran in view of Bardes under 35 U.S.C. §103(a), *inter alia*, Applicant

respectfully submits that claims 2-5, 7-9, 12-16, 18, 20-27, 29, 30, 32, 34, and 35 are also allowable over Cochran in view of Bardes under 35 U.S.C. §103(a).

Claims 1, 4, and 6 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cochran in view of Bardes and further in view of U.S. Patent No. 5,899,694 to Summer (hereinafter "Summer"). Applicant respectfully submits, however, that the combination of Cochran, Bardes, and Summer fails to suggest the subject matter of claims 1, 4, and 6 as a whole.

In the Office Action, the Examiner acknowledged that the combination of Cochran and Bardes fails to disclose a sheath that is fabricated from a flexible heat-shrinking polymer, as recited in claims 4 and 6, and relied on Summer for disclosure of this concept.<sup>1</sup>

As discussed above, the combination of Cochran and Bardes fails to suggest the subject matter of amended independent claim 1 as a whole. Assuming, *arguendo*, that the Examiner's purported characterization of Summer is accurate, including the sheath purportedly disclosed therein would fail to cure the aforedescribed deficiencies in the combination of Cochran and Bardes.

Accordingly, and for at least this reason, *inter alia*, Applicant respectfully submits the combination of Cochran, Bardes, and Summer fails to suggest the subject matter of amended independent claim 1 as a whole, and therefore, that amended independent claim 1 is allowable

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<sup>1</sup> Applicant believes that the Examiner inadvertently, but mistakenly, included claim 1 in the rejection under 35 U.S.C. §103(a) over Cochran in view of Bardes and Summer, in that independent claim 1 does not recite the sheath purportedly disclosed in Summer. However, in the interests of responding fully to the rejection, Applicant will overlook the inclusion of claim 1, and the rejection will be addressed with respect to claims 1, 4, and 6.

over Cochran in view of Bardes and Summer under 35 U.S.C. §103(a) as presented herein. Since claims 4 and 6 depend either directly or indirectly from amended independent claim 1, and include each element recited therein, for at least the reasons that amended independent claim 1 is allowable over the combination of Cochran in view of Bardes and Summer under 35 U.S.C. §103(a), *inter alia*, Applicant respectfully submits that claims 4 and 6 are also allowable over the combination of Cochran in view of Bardes and Summer under 35 U.S.C. §103(a).

Claims 10 and 11 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cochran in view of Bardes and further in view of U.S. Patent No. 6,402,722 to Snow *et al.* (hereinafter "Snow"). Applicant respectfully submits, however, that the combination of Cochran, Bardes, and Snow fails to suggest the subject matter of claims 10 and 11 as a whole.

In the Office Action, the Examiner acknowledged that the combination of Cochran and Bardes fails to disclose "a cord operatively connected to the tear line for facilitating the tearing of the sheath along the tear line," as recited in claim 10, and relied on Snow for disclosure of this concept.

As previously discussed, the combination of Cochran and Bardes fails to suggest the subject matter of amended independent claim 1 as a whole. Assuming, *arguendo*, that the Examiner's purported characterization of Snow is accurate, including the cord purportedly disclosed therein would fail to cure the aforescribed deficiencies in the combination of Cochran and Bardes.

Accordingly, and for at least this reason, *inter alia*, Applicant respectfully submits the combination of Cochran, Bardes, and Snow fails to suggest the subject matter of amended independent claim 1 as a whole, and therefore, that amended independent claim 1 is allowable over Cochran in view of Bardes and Snow under 35 U.S.C. §103(a) as presented herein. Since claims 10 and 11 depend either directly or indirectly from amended independent claim 1, and include each element recited therein, for at least the reasons that amended independent claim 1 is allowable over Cochran in view of Bardes and Snow under 35 U.S.C. §103(a), *inter alia*, Applicant respectfully submits that claims 10 and 11 are also allowable over Cochran in view of Bardes and Snow under 35 U.S.C. §103(a).

Claim 17 was rejected under 35 U.S.C. §103(a) as being unpatentable over Cochran in view of Bardes and further in view of U.S. Patent No. 5,480,404 to Kammerer, *et al.* (hereinafter "Kammerer"). Applicant respectfully submits, however, that the combination of Cochran, Bardes, and Kammerer fails to suggest the subject matter of claim 17 as a whole.

In the Office Action, the Examiner acknowledged that the combination of Cochran and Bardes fails to disclose a bag having a trapezoidal shape, as substantially recited in claim 17, and relied on Kammerer for disclosure of this concept.

As previously discussed, the combination of Cochran and Bardes fails to suggest the subject matter of amended independent claim 1 as a whole. Assuming, *arguendo*, that the Examiner's purported characterization of Kammerer is accurate, including the trapezoidal bag

purportedly disclosed therein would fail to cure the aforescribed deficiencies in the combination of Cochran and Bardes.

Accordingly, and for at least this reason, *inter alia*, Applicant respectfully submits the combination of Cochran, Bardes, and Kammerer fails to suggest the subject matter of amended independent claim 1 as a whole, and therefore, that amended independent claim 1 is allowable over Cochran in view of Bardes and Kammerer under 35 U.S.C. §103(a) as presented herein. Since claim 17 depends directly from amended independent claim 1, and includes each element recited therein, for at least the reasons that amended independent claim 1 is allowable over Cochran in view of Bardes and Kammerer under 35 U.S.C. §103(a), *inter alia*, Applicant respectfully submits that claim 17 is also allowable over Cochran in view of Bardes and Kammerer under 35 U.S.C. §103(a).

In view of the amendments to the claims effected herein, and the foregoing remarks and arguments, Applicant respectfully submits that claims 1-35 are allowable over the references of record, and accordingly, respectfully requests reconsideration and allowance of these claims.

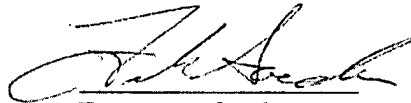
Should the Examiner have any questions concerning the present Amendment, or feel that an interview would be helpful in resolving any outstanding matters, the Examiner is sincerely invited to contact Applicant's undersigned attorney whenever convenient.

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Docket: 2786 (203-3098 PCT US)  
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Response to Office Action  
mailed January 9, 2009

An early and favorable response on the merits is earnestly requested.

Respectfully submitted,



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